

**Amendments to the Drawings:**

Please replace originally submitted drawing sheets 1-2 of this application with the enclosed drawing replacement sheets 1-2 enclosed herewith. In response to the drawings objections, Figures 1 and 2 have been amended to show reference numeral 4.

## REMARKS/ARGUMENTS

The following remarks are submitted in response to the Office Action dated June 25, 2008. Reconsideration and allowance are respectfully requested in view of the following remarks.

### ***1. The Drawing Objections***

In response to the drawings objections, enclosed is a set of replacement sheets in which Figures 1 and 2 have been amended to show reference numeral 4.

### ***2. The Prior Art Rejection***

#### **i. The 35 U.S.C. §102 Rejection in view of Cherif-Cheikh**

Claims 10-13 and 21 have been rejected pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,902,543 (hereinafter “Cherif-Cheikh”).

Cherif-Cheikh discloses a syringe device for reconstituting a solution, suspension or dispersion. The syringe device includes a container 11 which stores a solvent, a transfer needle 18 and a second container 13 for storing a lyophilizate (See col. 7, lines 64-67; col. 8, lines 1-11). Cherif-Cheikh, however, does not appear to disclose all the required limitations of independent claim 10. Namely, Cherif-Cheikh fails to disclose:

- (1) “at least two protrusions being formed on an inner side of the bracket, said protrusions being in contact with the bottom opening of the solvent bottle”;
- (2) “at least two protrusions are formed on an inner side of the bracket, the protrusions being in contact with the bottom opening of the solute bottle”;
- (3) “a bracket that is positioned in a bottom opening of the solvent bottle”; and
- (4) “a solvent bottle that is positioned within said sleeve.”

Cherif-Cheikh fails to disclose at least two protrusions on an inner side of the brackets in contact with the bottom opening of the solute bottle and solvent bottle, as required by

independent claim 10. Notably, Cherif-Cheikh fails to mention and none of the figures show a pair of protrusions on the brackets for receiving the sealing caps 22 and 28. At the most, the cross-sectional diagrams of the device, shown in Figure 9 and 10, only suggest that the bracket may have a single lip or rim. Cherif-Cheikh does not, however, disclose at least two protrusions located on an inner surface of the brackets. Therefore it fails to disclose all the elements required by independent claim 10.

Applicant also wishes to preemptively assert that the claimed protrusions are not obvious features. In the present application, protrusions 25 and 28 may be a plurality of fins, hooks or nipples (See page 8, line 29; page 9, line 28; page 10, line 1) which function to retain the solute and solvent bottles in their respective brackets. Furthermore, the protrusions prevent the solvent and solute bottle from being removed from the syringe and subsequently reused. Therefore, the protrusions help to ensure that the syringe is only used once and is subsequently discarded to avoid any risk of contamination that results from reuse of the solvent bottle, solute bottle or syringe (See page 9, lines 20-23). By contrast, Cherif-Cheikh is structured to enable removal and replacement of solvent container 11 (See col. 10, lines 50-56).

Cherif-Cheikh also fails to disclose “a bracket positioned in a bottom opening of the solvent bottle”, as required by independent claim 10. As shown in Figures 1 and Figures 8B-8C, Cherif-Cheikh discloses a lyophilizate container 13 which includes a piston 29, a transfer needle 18, a transfer mechanism, and a locking mechanism (See col. 9, lines 23-30, 54-68). The transfer mechanism includes a surface for receiving solvent container 11, which corresponds to the bracket component of the present application. However, the transfer mechanism is constructed as an integral part of lyophilizate container 13 and is separated from the bottom opening of the solvent container. Cherif-Cheikh explicitly states that solvent container 11 is distal to and may be “stored and packed away from the rest of the syringe” (See col. 8, lines 12-16, 24; Figure 1). Therefore, Cherif-Cheikh fails to disclose a bracket that is positioned in a bottom opening of the solvent bottle.

Cherif-Cheikh also fails to disclose a solvent bottle positioned within the sleeve, as required by claim 1. Rather Cherif-Cheikh only discloses that lyophilizate container 13 is positioned within sleeve 19.

Cherif-Cheikh also fails to anticipate independent claim 21 for failure to disclose each of the claim elements discussed above with respect to independent claim 1.

Furthermore, with respect to claim 1, Cherif-Cheikh also fails to disclose a projecting jacket which covers the second sealing plug, bracket and syringe needle. In describing Figure 1, Cherif-Cheikh discloses a cap 36 attached to a distal end of sleeve 34/base 35 (See col. 10, lines 30-31; Figures 1, 7-9, 13). Cap 36 is never disclosed or shown as extending past a distal end of sleeve 34, covering sleeve 34 (i.e. the bracket of the present invention) or covering stopper 27 (i.e. the sealing plug of the present invention). Cap 36 is merely shown and discussed as covering the needle tip of the syringe. Cherif-Cheikh also discloses a lock 37 that comprises an arm which extends from cap 36 and attaches to a point on the distal end of sleeve 34 (See Figure 1; col. 14, lines 37-38). Because lock 37 is constructed as a thin arm member, it does not fully cover needle 20, sleeve 34 or stopper 27; nor does lock 37 even extend over a length of sleeve 34 or stopper 27.

For the reasons presented above, Cherif-Cheikh fails to disclose all the elements required by independent claims 10 and 21. Consequently, Cherif-Cheikh also fails to anticipate the claims that depend therefrom.

**ii. The 35 U.S.C. §103(a) Rejection in view of Cherif-Cheikh and Mohammad**

Claims 14-16 have been rejected, pursuant to 35 U.S.C. 103(a), as being obvious over Cherif-Cheikh in view of U.S. Patent No. 6,776,775 (hereinafter "Mohammad"). MPEP §2143 sets forth the three basic requirements that are necessary to support a prima facie case of obviousness for a §103 rejection:

**2143 Basic Requirements of a Prima Facie Case of Obviousness**

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The proposed combination of Cherif-Cheikh in view of Mohammad that was applied in the Office Action fails to set forth all the limitations of independent claim 10 as well as dependent claims 14-16.

Mohammad discloses a hypodermic syringe needle assembly including a container wall 9 for housing a syringe barrel. Wall 9 includes a longitudinal slot 10 with opposing side slots 10a and 10b.

Mohammad, however, does not disclose: (1) at least two protrusions on an inner side of the bracket that are in contact with the bottom opening of the solute bottle; (2) at least two protrusions on an inner side of the bracket that are in contact with the bottom opening of the solvent bottle; (3) a bracket positioned in a bottom opening of the solvent bottle; (4) a solvent bottle positioned within the sleeve; or (5) a projecting jacket which covers the second sealing plug, bracket and syringe needle. Therefore Mohammad fails to correct the deficiencies of Cherif-Cheikh, and the combination of Cherif-Cheikh in view of Mohammad does not render obvious independent claim 10 or any claims that depend therefrom.

Cherif-Cheikh in view of Mohammad further fails to disclose all the limitations of dependent claim 14. Namely, the references fail to teach:

- (1) “a first restricting slot and a second restricting slot, both of which are upside-down ‘L’-shaped”;
- (2) “two tongues are arranged on two sides of a lower edge of the plunger sleeve so as to be symmetrical to the axis thereof”;
- (3) “plunger sleeve being provided with buckles ... two tongues are arranged on two sides of a lower edge of the plunger sleeve”; and

- (4) “two slots corresponding to the positions of the tongues are arranged on the two sides of the upper edge of the inner sleeve so as to be symmetrical to the axis thereof.”

Contrary to the assertion of the Office Action, slots 10, 10a and 10b of Mohammad do not form two upside-down L shaped restricting slots. As shown in Figures 2-3, 5, 11-12 and 19-21, these slots form a half rectangle with opposing ends 10a and 10b. When viewed from any one perspective point, Mohammad shows two opposing sides of a rectangular slot, rather than two upside down Ls, as required by claim 14.

Additionally, the Office Action cites rigid tongue 9b, as illustrated in Figure 10(b), for meeting the tongue limitation of claim 14. Mohammad, however, only discloses one rigid tongue 9b and therefore fails to disclose two tongues which are oriented symmetrical to the axis of the plunger sleeve, as required by claim 14.

Mohammad also fails to disclose that the tongues and buckles are located on the plunger sleeve (i.e. syringe plunger 18 as disclosed by Mohammad). By contrast, cited pin 7 is located on sleeve 3 and rigid tongue 9b is located on tubular wall 9 of the container (See col. 11, lines 8-9). Neither of these structures is located on syringe plunger 18, as required by claim 14.

Mohammad also fails to disclose two slots located on and symmetrical to an axis of an inner sleeve, wherein the two slots correspond to the two tongues. According to the claim 14, these slots are located on an inner sleeve and are distinct from the restriction slots, which are located on the plunger sleeve. Contrary to the position asserted in the Office Action, slots 10a and 10b may not represent both the restriction slots and the inner sleeve slots because they are located on different structures of the syringe device. Therefore, Mohammad does not disclose a separate pair of inner sleeve slots, as required by claim 14.

Moreover, there is no reasonable expectation of success or motivation to combine the teachings of Cherif-Cheikh with that of Mohammad. According to the Office Action, it would be obvious to combine the teachings of Cherif-Cheikh's reconstitution syringe device with Mohammad's slots, tongue and buckle structures in order to provide “a locking mechanism within the syringe body.” Mohammad's locking structure is directed to a means for retracting

and securing the syringe tip to prevent needle sticks (See col. 1, lines 31-32). The present invention, however, has a projecting jacket which already provides a means for preventing accidental needle sticks. Therefore there is no motivation to incorporate a retracting needle tip design. Furthermore, in view of Cherif-Cheikh's solvent container, lyophilizate container and complex structure connecting the these containers, there is no reasonable expectation of success that it would be possible to further incorporate the retracting needle tip structures of Mohammad without interfering with or hindering the structure and method of reconstituting a solution, as taught by Cherif-Cheikh.

For the reasons presented above, claim 14 and the claims which depend therefrom are not rendered obvious over Cherif-Cheikh in view of Mohammad.

**iii. The 35 U.S.C. §103(a) Rejection in view of Cherif-Cheikh, Mohammad and Peterson**

Claims 17-20 are rejected under 35 U.S.C. §103(a) as being rendered obvious by Cherif-Cheikh in view of Mohammad and U.S. Patent No. 5,520,639 (hereinafter "Peterson").

Peterson discloses a needleless hypodermic device including viewing ports 722. Notably, however, Peterson fails to disclose: (1) at least two protrusions on an inner side of the bracket that are in contact with the bottom opening of the solute bottle; (2) at least two protrusions on an inner side of the bracket that are in contact with the bottom opening of the solvent bottle; (3) a bracket positioned in a bottom opening of the solvent bottle; (4) a solvent bottle positioned within the sleeve; or (5) a projecting jacket which covers the second sealing plug, bracket and syringe needle. Therefore Peterson fails to correct the deficiencies of Cherif-Cheikh in view of Mohammad; The combination of Cherif-Cheikh in view of Mohammad and Peterson does not render obvious independent claims 10 or any claims that depend therefrom.

**3. Conclusion**

Applicant has made an earnest effort to place this application in condition for allowance. If Examiner Hayman feels that a telephone interview would expedite prosecution of this patent

application, he is respectfully invited to telephone the undersigned at 215-599-0600. Contact with the undersigned via electronic mail at [gdoe@patentwise.com](mailto:gdoe@patentwise.com) is hereby authorized<sup>1</sup> per MPEP 502.03.

Respectfully submitted,

/GSD/

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Date: September 24, 2008

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<sup>1</sup> Recognizing that Internet communications are not secure, I hereby authorize the USPTO to communicate with me concerning any subject matter of this application by electronic mail. I understand that a copy of these communications will be made of record in the application file.